



UNITED STATE DEPARTMENT OF COMMERCE Patent and Trademark Office



NOTICE OF ALLOWANCE AND ISSUE FEE DUE

HM22/0112

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APPLICATION NO.		FILING DATE	TOTAL CLAIMS	EXAMINER AND GROUP ART UNIT		DATE MAILED .
	08/888.057	7 07/03/97	7 026	CROUCH, D	16	32 01/12/1
First Named Applicant	STICE.		35	USC 154(b) term ext. =	0	Days.

TITLE OF INVENTION

CLONING PIGS USING DONOR NUCLEI FROM NON-QUIESCENT DIFFERENTIATED CELLS

1	ATTY'S DO	CKET NO.	CLASS-SUB	BCLASS	BATCH NO.	APPLN. T	YPE	SMALL ENT	ΙΤΥ	FEE DUE		DATE DUE
	1	000270~	012	800-0	24.000	A57	UT	LITY	YES	s \$620.	.00	04/12/0

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED.

THE ISSUE FEE MUST BE PAID WITHIN <u>THREE MONTHS</u> FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED.

HOW TO RESPOND TO THIS NOTICE:

- I. Review the SMALL ENTITY status shown above. If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:
 - A. If the status is changed, pay twice the amount of the FEE DUE shown above and notify the Patent and Trademark Office of the change in status, or
 - B. If the status is the same, pay the FEE DUE shown above.
- If the SMALL ENTITY is shown as NO:
- A. Pay FEE DUE shown above, or
- B. File verified statement of Small Entity Status before, or with, payment of 1/2 the FEE DUE shown above.
- II. Part B-Issue Fee Transmittal should be completed and returned to the Patent and Trademark Office (PTO) with your ISSUE FEE. Even if the ISSUE FEE has already been paid by charge to deposit account, Part B Issue Fee Transmittal should be completed and returned. If you are charging the ISSUE FEE to your deposit account, section "4b" of Part B-Issue Fee Transmittal should be completed and an extra copy of the form should be submitted.
- III. All communications regarding this application must give application number and batch number.

 Please direct all communications prior to issuance to Box ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

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Notice of Allowability

Application No. 08/888,057

Applicant(s)

Stice et al.

Examiner

Deborah Crouch

Group Art Unit 1632

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance and Issue Fee Due or other appropriate communication will be mailed in due course. |X| This communication is responsive to _the amendment filed November 1, 2000_ The allowed claim(s) is/are 1-17, 24, 25, 61-63, 80, and 83-85 ☐ The drawings filed on ______ are acceptable. Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d). ☐ All ☐ Some* None of the CERTIFIED copies of the priority documents have been ☐ received. received in Application No. (Series Code/Serial Number) received in this national stage application from the International Bureau (PCT Rule 17.2(a)). *Certified copies not received: Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e). A SHORTENED STATUTORY PERIOD FOR RESPONSE to comply with the requirements noted below is set to EXPIRE THREE MONTHSROM THE "DATE MAILED" of this Office action. Failure to timely comply will result in ABANDONMENT of this application. Extensions of time may be obtained under the provisions of 37 CFR 1.136(a). ☐ Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL APPLICATION, PTO-152, which discloses that the oath or declaration is deficient. A SUBSTITUTE OATH OR DECLARATION IS REQUIRED. □ Applicant MUST submit NEW FORMAL DRAWINGS because the originally filed drawings were declared by applicant to be informal. including changes required by the Notice of Draftsperson's Patent Drawing Review, PTO-948, attached hereto or to Paper No. including changes required by the proposed drawing correction filed on ______, which has been approved by the examiner. including changes required by the attached Examiner's Amendment/Comment. Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the reverse side of the drawings. The drawings should be filed as a separate paper with a transmittal lettter addressed to the Official Draftsperson. □ Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL. Any response to this letter should include, in the upper right hand corner, the APPLICATION NUMBER (SERIES CODE/SERIAL NUMBER). If applicant has received a Notice of Allowance and Issue Fee Due, the ISSUE BATCH NUMBER and DATE of the NOTICE OF ALLOWANCE should also be included. Attachment(s) X Notice of References Cited, PTO-892 ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). Notice of Draftsperson's Patent Drawing Review, PTO-948 Notice of Informal Patent Application, PTO-152 X) Interview Summary, PTO-413 X Examiner's Amendment/Comment □ Examiner's Comment Regarding Requirement for Deposit of Biological Material ☐ Examiner's Statement of Reasons for Allowance

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An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Ms. Robin Teskin on December 18, 2000.

- 1. Please rewrite claims 1, 11, 24, 61 and 80 as follows:
 - 1. A method of cloning a pig, comprising:
- (i) inserting a non-quiescent differentiated pig cell or non-quiescent differentiated pig cell nucleus into an enucleated pig oocyte, under conditions suitable for the formation of a nuclear transfer
 (NT) unit;
 - (ii) activating the resultant NT unit; and
 - (iii) transferring said activated NT unit to a host pig such that the NT unit develops into a

fetus

- 11. The method according to claim 1, wherein the differentiated pig cell is a fetal cell or differentiated pig cell nucleus is isolated from a fetal cell.
- The method according to claim 5, which further comprises combining a cell of the NT unit with an embryo to produce a chimeric embryo, which is then transferred to a host pig such that the chimeric embryo develops into a chimeric fetus.
 - 2/ 61. A method of cloning a pig, comprising:
- (i) inserting a non-quiescent differentiated pig CICM cell or non-quiescent differentiated pig CICM cell nucleus into an enucleated pig oocyte, under conditions suitable for the formation of a nuclear transfer (NT) unit;
 - (ii) activating the resultant NT unit; and
- (iii) transferring said activated NT unit to a host pig such that the NT unit develops into a fetus.

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20_80. The method according to claim 1 wherein said non-quiescent differentiated pig cell has been expanded in culture or said non-quiescent differentiated pig cell nucleus is isolated from non-quiescent differentiated pig cell that has been expanded in culture.

- 2. In claims 3,6,7,8,9,10 and 11, before "cell nucleus" insert --differentiated pig--.
- 3. In claim 10, before second "cell nucleus" insert --adult--.
- 4. In claims 13,14 and 15, delete "fused".
- 5. In claim 15, delete "derived" and insert -- isolated --.
- 6. Please enter the following new claims:

29. A method of producing a non-human mammalian embryo by nuclear transfer comprising transplantation of a non-human mammalian cell or a nucleus of a non-human mammalian cell into an enucleated oocyte of the same species as the donor cell or donor cell nucleus, activation of the recipient oocyte containing the donor cell or donor cell nucleus, and incubation of the activated oocyte to produce an embryo, wherein the donor cell is a non-quiescent mammalian differentiated cell or wherein the donor nucleus is from a non-quiescent mammalian differentiated cell.

25 84. The method according to claim 1 wherein said non-human mammalian embryo is porcine.

26.85. The method according to claim 1 wherein said non-human mammalian embryo is an ungulate.

- 7. Cancel claims 18-23,26-60,64-79,81 and 82 without prejudice or disclaimer for further prosecution.
- 8. The title has been changed to: --Cloning Pigs Using Donor Nuclei from Non-Quiescent Differentiated Cells--.
- 9. The claims have been renumbered as original claims 1-17 = allowed claims 1-17; 24 and 25 = 18 and 19; 80 = 20; 61-63 = 21-23; and 83-85 = 24-26.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Crouch, Ph.D. whose telephone number is (703) 308-1126. The examiner's SPE is

Any inquiry of a general nature or relating to the status of this application should be directed to the Art Unit Patent Analyst, Kay Pinkney, whose telephone number is (703) 305-3553.

The fax number is (703) 308-4242.

Karen Hauda, whose telephone number is (703) 305-6608.

DEBORAH CROUCH PRIMARY EXAMINER

GROUP 1800 1630

Deboral anch

Dr. D. Crouch January 2, 2001

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<u>ATTACHMENT TO AND MODIFICATION OF</u> <u>NOTICE OF ALLOWABILITY (PTO-37)</u>

(November, 2000)

NO EXTENSIONS OF TIME ARE PERMITTED TO FILE CORRECTED OR FORMAL DRAWINGS, OR A SUBSTITUTE OATH OR DECLARATION, notwithstanding any indication to the contrary in the attached Notice of Allowability (PTO-37).

If the following language appears on the attached Notice of Allowability, the portion lined through below is of no force and effect and is to be ignored¹:

A SHORTENED STATUTORY PERIOD FOR RESPONSE to comply with the requirements noted below is set to EXPIRE THREE MONTHS FROM THE "DATE MAILED" of this Office action. Failure to comply will result in ABANDONMENT of this application. Extensions of time may be obtained under the provisions of 37 CFR 1-136(a)

Similar language appearing in any attachments to the Notice of Allowability, such as in an Examiner's Amendment/Comment or in a Notice of Draftperson's Patent Drawing Review, PTO-948, is also to be ignored.

¹ The language which is crossed out is contrary to amended 37 CFR 1.85(c) and 1.136. See "Changes to Implement the Patent Business Goals", 65 Fed. Reg. 54603, 54629, 54641, 54670, 54674 (September 8, 2000), 1238 Off. Gaz. Pat. Office 77, 99, 110, 135, 139 (September 19, 2000).